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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,231	06/26/2000	Han-Cheng Zhang	ORT-1236	3016

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/20/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,231

Applicant(s)

ZHANG ET AL.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 12-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) #2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-8, 10, and 11 are rejected under 35 U.S.C. 103 (a) over Forbes et al. (PCT International Publication Number WO 93/18026) (September 16, 1993) over Hoekstra et al. (U.S. Patent 6,017,890) (January 25, 2000).

Forbes et al teach a compound of the formula (I) with all the limitations of claims 1-8 but devoid of A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine. (Abstract and page 1, lines 25-30, and page 2, line 1 to page 14, line 23).

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Forbes et al also teach a pharmaceutically acceptable salts thereof (Abstract and claims 33, 36 and 37).

Forbes et al do not teach a compound with A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine.

Hoekstra et al. teach a compound with A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine (Column 1, lines 8-35 and Claim 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine of Hoekstra et al. in the compound of the formula (I) with all the limitations of claims 1-8 but devoid of A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine of Forbes et al. since Hoekstra et al. states, "Hence, antagonists of the thrombin receptor based on SFLLRN are useful in antagonizing these protease-activated receptors and as such may be used to treat platelet mediated thrombotic disorders such as myocardial infarction, stroke, restenosis, angina, atherosclerosis, and ischemic attacks by virtue of their ability to prevent platelet aggregation (Column 1, lines 29-35)." An ordinary practitioner would have been motivated to combine and substitute the A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine of Hoekstra et al. in the compound of the formula (I) with all the limitations of claims 1-8 but devoid of A1 and A2, which are D- or L- amino acids selected from arginine, serine, leucine or phenyl alanine of Forbes et al. in order to achieve the express advantages, as

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noted by Hoekstra et al, of antagonists of the thrombin receptor based on SFLLRN which are useful in antagonizing these protease-activated receptors and as such may be used to treat platelet mediated thrombotic disorders such as myocardial infarction, stroke, restenosis, angina, atherosclerosis, and ischemic attacks by virtue of their ability to prevent platelet aggregation.

Response to Arguments

3. In response to arguments, initialed copy of 1449 listing USPatent 6,017,890 is provided herewith. Any inconvenience is hereby regretted.

Applicant's arguments filed on August 19, 2002 have been fully considered but they are not persuasive. .

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this

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case, Hoekstra et al provides strong motivation as Hoekstra et al. states, "Hence, antagonists of the thrombin receptor based on SFLLRN are useful in antagonizing these protease-activated receptors and as such may be used to treat platelet mediated thrombotic disorders such as myocardial infarction, stroke, restenosis, angina, atherosclerosis, and ischemic attacks by virtue of their ability to prevent platelet aggregation (Column 1, lines 29-35)."

In response to applicant's argument that the applicant has an advantage other than the references cited in the office action, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the compound of the claimed invention have PAR-1 activity against other serotonin receptors whereas Forbes reference teaches 5-HTIC receptor antagonist, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant argues that Forbes reference does not teach the R1 and R3 substituents of the claimed invention. Applicant argues that the specific substituents of Forbes reference (C1-C6

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alkyl) is different than the (CH₂)_m attached to a arC₁-C₈ alkyl of the claimed invention..

Applicant argues that because Forbes has a preferred embodiment of C₁-C₆ alkyl, Forbes is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971)." MPEP 2123 also states " A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories* , 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Forbes has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Forbes reference uses C₁-C₆ alkyl at R₁ and R₃ positions, the property of substituting (CH₂)_m attached to a arC₁-C₈ alkyl at these positions is inherently present in this chemically and structurally identical molecule. For example, Forbes teaches that suitable alkyloxycarbonyl groups can be inserted in the R₁ position by the conventional reaction process (Page 7, lines 14-30). Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this

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case, any typical N-protecting groups can be substituted at the R1 and R3 position as explicitly suggested by Forbes.

Therefore, all the rejections made in the first office action are hereby properly maintained.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818.

The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-


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7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237

Arun Chakrabarti,

Patent Examiner,

September 11, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600